## **Complete Summary**

#### **GUIDELINE TITLE**

Management of adults with major depression.

## BIBLIOGRAPHIC SOURCE(S)

Michigan Quality Improvement Consortium. Management of adults with major depression. Southfield (MI): Michigan Quality Improvement Consortium; 2004 Jan. 1 p.

#### **GUIDELINE STATUS**

Note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary.

#### \*\* REGULATORY ALERT \*\*

#### FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

On July 1, 2005, in response to recent scientific publications that report the possibility of increased risk of suicidal behavior in adults treated with antidepressants, the U.S. Food and Drug Administration (FDA) issued a Public Health Advisory to update patients and healthcare providers with the latest information on this subject. Even before the publication of these recent reports, FDA had already begun the process of reviewing available data to determine whether there is an increased risk of suicidal behavior in adults taking antidepressants. The Agency has asked manufacturers to provide information from their trials using an approach similar to that used in the evaluation of the risk of suicidal behavior in the pediatric population taking antidepressants. This effort will involve hundreds of clinical trials and may take more than a year to complete. See the <u>FDA Web site</u> for more information.

#### **COMPLETE SUMMARY CONTENT**

\*\* REGULATORY ALERT \*\*

SCOPE

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## SCOPE

#### DISEASE/CONDITION(S)

Major depression

## **GUIDELINE CATEGORY**

Diagnosis Management Risk Assessment Treatment

#### CLINICAL SPECIALTY

Family Practice Internal Medicine Psychiatry Psychology

#### INTENDED USERS

Advanced Practice Nurses Health Plans Physician Assistants Physicians

## GUIDELINE OBJECTIVE(S)

- To achieve significant, measurable improvements in the management of major depression through the development and implementation of common evidence-based clinical practice guidelines
- To design concise guidelines that are focused on key management components of major depression to improve outcomes

#### TARGET POPULATION

- Adults 18 years or older who have been diagnosed or are at high risk for major depressive disorder
- Individuals diagnosed with major depression
- Individuals prescribed antidepressant medication for major depression

#### INTERVENTIONS AND PRACTICES CONSIDERED

- 1. Obtain history of:
  - Depression or suicide attempts (family or personal history)
  - Recent stressful life events
  - Chronic illnesses, chronic pain, unexplained somatic complaints, symptoms of fatigue, malaise, irritability, or sadness
  - Current alcohol or substance abuse
- 2. Assess whether Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria for major depression are met
- 3. Assess risk of suicide
- 4. Initiate antidepressant medication for a minimum of 6 months
- 5. Refer to and coordinate with behavioral health specialist

#### MAJOR OUTCOMES CONSIDERED

Not stated

## METHODOLOGY

#### METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

#### DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The Michigan Quality Improvement Consortium (MQIC) project leader conducts a search of current literature in support of the guideline topic. Computer database searches are used to identify published studies and existing protocols and/or clinical practice guidelines on the selected topic. A database such as MEDLINE and two to three other databases are used. The Michigan Quality Improvement Consortium project leader collects and documents search results (i.e., citations, abstracts and full text articles).

#### NUMBER OF SOURCE DOCUMENTS

Not stated

## METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

#### RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence for the Most Significant Recommendation

- A. Randomized controlled trials
- B. Controlled trials, no randomization
- C. Observational studies
- D. Opinion of expert panel

#### METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

**Expert Consensus** 

## DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Using the health plan guideline summaries and information obtained from the literature search, the Michigan Quality Improvement Consortium (MQIC) director and/or project leader prepare a draft guideline for review by the MQIC Medical Directors.

The draft guideline and health plan guideline summaries are distributed to the MQIC Medical Directors for review and discussion at their next committee meeting.

The review/revision cycle may be conducted over several meetings before consensus is reached. Each version of the draft guideline is distributed to the MQIC Medical Directors, Measurement, and Implementation committee members for review and comments. All feedback received is distributed to the entire membership.

Once the MQIC Medical Directors achieve consensus on the draft guideline, it is considered approved for external distribution to practitioners with review and comments requested.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Once the Michigan Quality Improvement Consortium (MQIC) Medical Directors achieve consensus on the draft guideline, it is considered approved for external distribution to practitioners with review and comments requested.

The Michigan Quality Improvement Consortium director also forwards the approved guideline draft to presidents of the appropriate state medical specialty societies for their input. All feedback received from external reviews is presented for discussion at the next Michigan Quality Improvement Consortium Medical Directors Committee meeting. In addition, physicians are invited to attend the committee meeting to present their comments.

#### RECOMMENDATIONS

#### MAJOR RECOMMENDATIONS

Note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary. The recommendations that follow are based on the previous version of the guideline.

The level of evidence grades (A-D) are provided for the most significant recommendations and are defined at the end of the "Major Recommendations" field.

**Detection and Diagnosis** 

Maintain high index of suspicion for depressive symptom is persons with:

- Family or personal history of depression or suicide attempts [A]
- Recent stressful life events (e.g., post-partum state) and lack of social supports
- Chronic illnesses, chronic pain, unexplained somatic complaints, symptoms of fatigue, malaise, irritability, or sadness
- Current alcohol or substance abuse

Assess if Diagnostic and Statistic Manual of Mental Disorders - Fourth Edition (DSM-IV) criteria<sup>1</sup> for major depression are met. [A]

Eligible Population

Adults 18 years or older who have been diagnosed or are at high risk for major depressive disorders

Frequency

At each evaluation where the patient's high-risk status, symptoms, or signs raise suspicion of current or uncontrolled depression

<sup>&</sup>lt;sup>1</sup> DSM-IV Criteria: Depressed mood most of the day, nearly every day and/or markedly diminished interest or pleasure in almost all activities most of the day in conjunction with at least four of the following symptoms present for at least two

(2) weeks: Significant weight loss/gain; Insomnia/hypersomnia; Feelings of worthlessness; Fatigue/loss of energy; Psychomotor slowing/agitation; Thoughts of suicide/death; Impaired concentration/indecisiveness. (Recognition may be increased with the use of a validated screening tool, e.g., Harvard Department of Psychiatry National Depression Screening Day Scale [HANDS], Center for Epidemiologic Studies - Depression Scale [CES-D] Revised, Zung, Primary Care Evaluation of Mental Disorders [PRIME-MD])

Screening for Suicide Risk

Assess risk of suicide by direct questioning about suicide thinking, suicide planning, potential means, and personal/family history of suicide attempts.

Eligible Population

Individuals diagnosed with major depression

Frequency

At each encounter addressing depression

Management of Patients who are Prescribed Antidepressant Medication

- Initiate antidepressant medication following manufacturer's recommended doses. [A]
- Monitor medication frequently and adjust to a therapeutic level not to exceed the highest recommended dose. [D] Medication should not be abruptly discontinued.
- If response is unsatisfactory in 6 weeks at maximum recommended dosages, switch to another antidepressant medication.
- Continue antidepressant medication for a minimum of 6 months to prevent relapse. [A]
- For patients with recurrent major depression, continue medication for at least one year or longer at effective dosage. [B]

Eligible Population

Individuals prescribed antidepressant medication for major depression

Frequency

Medications for at least 6 months; schedule at least 3 follow-up office visits in first 12 weeks. [D]

Referral to, and Coordination with, Behavioral Health Specialist When:

- Identified or suspected risk of suicide
- Alcohol or substance abuse
- Primary physician not comfortable managing patient's depression
- Diagnosis is uncertain or complicated by other psychiatric factors
- Complex social situation

- Management is complex, response to medication is not optimal, or considering prescribing multiple agents
- Psychotherapy and/or hospitalization required

Eligible Population

Individuals prescribed antidepressant medication for major depression

Frequency

Following hospitalization for major depression, a Behavioral Health Specialist should see patients within 7 days of discharge.

#### **Definitions**:

Levels of Evidence for the Most Significant Recommendations

- A. Randomized controlled trials
- B. Controlled trials, no randomization
- C. Observational studies
- D. Opinion of expert panel

CLINICAL ALGORITHM(S)

None provided

#### EVIDENCE SUPPORTING THE RECOMMENDATIONS

### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence is provided for the most significant recommendations (See "Major Recommendations" field).

This guideline is based on several sources, including: Major Depression in Adults in Primary Care. Institute for Clinical Systems Improvement, 2003 (<a href="https://www.icsi.org">www.icsi.org</a>).

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

#### POTENTIAL BENEFITS

Through a collaborative approach to developing and implementing common clinical practice guidelines and performance measures for major depression, Michigan health plans will achieve consistent delivery of evidence-based services and better health outcomes. This approach also will augment the practice environment for physicians by reducing the administrative burdens imposed by compliance with diverse health plan guidelines and associated requirements.

#### POTENTIAL HARMS

## CONTRAINDICATIONS

#### **CONTRAINDICATIONS**

Not stated

#### QUALIFYING STATEMENTS

#### QUALIFYING STATEMENTS

This guideline lists core management steps for non-behavioral health specialists. Individual patient considerations and advances in medical science may supersede or modify these recommendations.

## IMPLEMENTATION OF THE GUIDELINE

#### DESCRIPTION OF IMPLEMENTATION STRATEGY

When consensus is reached on a final version of the guideline, a statewide mailing of the approved guideline is completed. The guideline is distributed to physicians in the following medical specialties:

- Family Practice
- General Practice
- Internal Medicine
- Other Specialists for which the guideline is applicable (e.g., endocrinologists, allergists, pediatricians, cardiologists, etc.)

#### IMPLEMENTATION TOOLS

Chart Documentation/Checklists/Forms

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

# INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

**IOM CARE NEED** 

Living with Illness

IOM DOMAIN

Effectiveness Patient-centeredness

## IDENTIFYING INFORMATION AND AVAILABILITY

## BIBLIOGRAPHIC SOURCE(S)

Michigan Quality Improvement Consortium. Management of adults with major depression. Southfield (MI): Michigan Quality Improvement Consortium; 2004 Jan. 1 p.

#### **ADAPTATION**

This guideline is based on several sources, including: Major Depression in Adults in Primary Care. Institute for Clinical Systems Improvement, 2003 (<a href="https://www.icsi.org">www.icsi.org</a>).

#### DATE RELEASED

2004 Jan

## GUIDELINE DEVELOPER(S)

Michigan Quality Improvement Consortium

## SOURCE(S) OF FUNDING

Michigan Quality Improvement Consortium

## **GUI DELI NE COMMITTEE**

Michigan Quality Improvement Consortium Medical Director's Committee

#### COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Physician representatives from participating Michigan Quality Improvement Consortium health plans, Michigan State Medical Society, Michigan Osteopathic Association, Michigan Association of Health Plans, Michigan Department of Community Health and Michigan Peer Review Organization

#### FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

#### **GUIDELINE STATUS**

Note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary.

#### **GUIDELINE AVAILABILITY**

Electronic copies of the updated guideline: Available in Portable Document Format (PDF) from the Michigan Quality Improvement Consortium Web site.

#### AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

Center for Epidemiologic Studies - Depression Scale [CES-D] Revised.
 Electronic copies available in Portable Document Format (PDF) from the Michigan Quality Improvement Consortium Web site.

#### PATIENT RESOURCES

None available

#### NGC STATUS

This NGC summary was completed by ECRI on December 10, 2004. The information was verified by the guideline developer on January 21, 2005. This summary was updated by ECRI on August 15, 2005, following the U.S. Food and Drug Administration advisory on antidepressant medications.

#### COPYRIGHT STATEMENT

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#### NGC DISCLAIMER

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